

OECD/SIDS

- ♦ ORGANIZATION FOR ECONOMIC
COOPERATION AND DEVELOPMENT
- ♦ SCREENING INFORMATION DATA
SET

Co-operation on Existing Chemicals

COUNCIL ACTS

- ❑ **1990 Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/Final]**

“DECIDES that Member countries shall co-operatively investigate high production volume (HPV) chemicals in order to identify those which are potentially hazardous to the environment and/or to the health of the general public or workers

“DECIDES that Member countries shall(...) co-operatively select the HPV chemicals (...) agree upon basic data... and co-operatively make an initial assessment...”

SIDS Participants

Initial Member Country Participants (1990)

**Austria Belgium Canada Denmark
Finland France Germany Italy Japan
Netherlands Sweden Switzerland United
Kingdom United States**

Additional Member Country Participants

**Australia Czech Republic Greece Korea
Ireland Norway Spain Slovak Republic**

Co-operation on Existing Chemicals

Council Act C(90) 163

Member countries DECIDE that they cooperatively:

- ☐ **select HPV chemicals;**
- ☐ **acquire SIDS;**
- ☐ **make initial assessments**

HPV Chemicals Programme

Sharing the Burden

- ☐ **Duplication is avoided**
- ☐ **Resources are saved**
- ☐ **More chemicals have internationally acceptable assessments**

HPV Chemical Definition

U.S.

- Manufactured/imported chemical in volume greater than 1 million lbs/year.

E.U./SIDS

- Manufactured/imported chemical in volume greater than 2.2 million lbs/year.

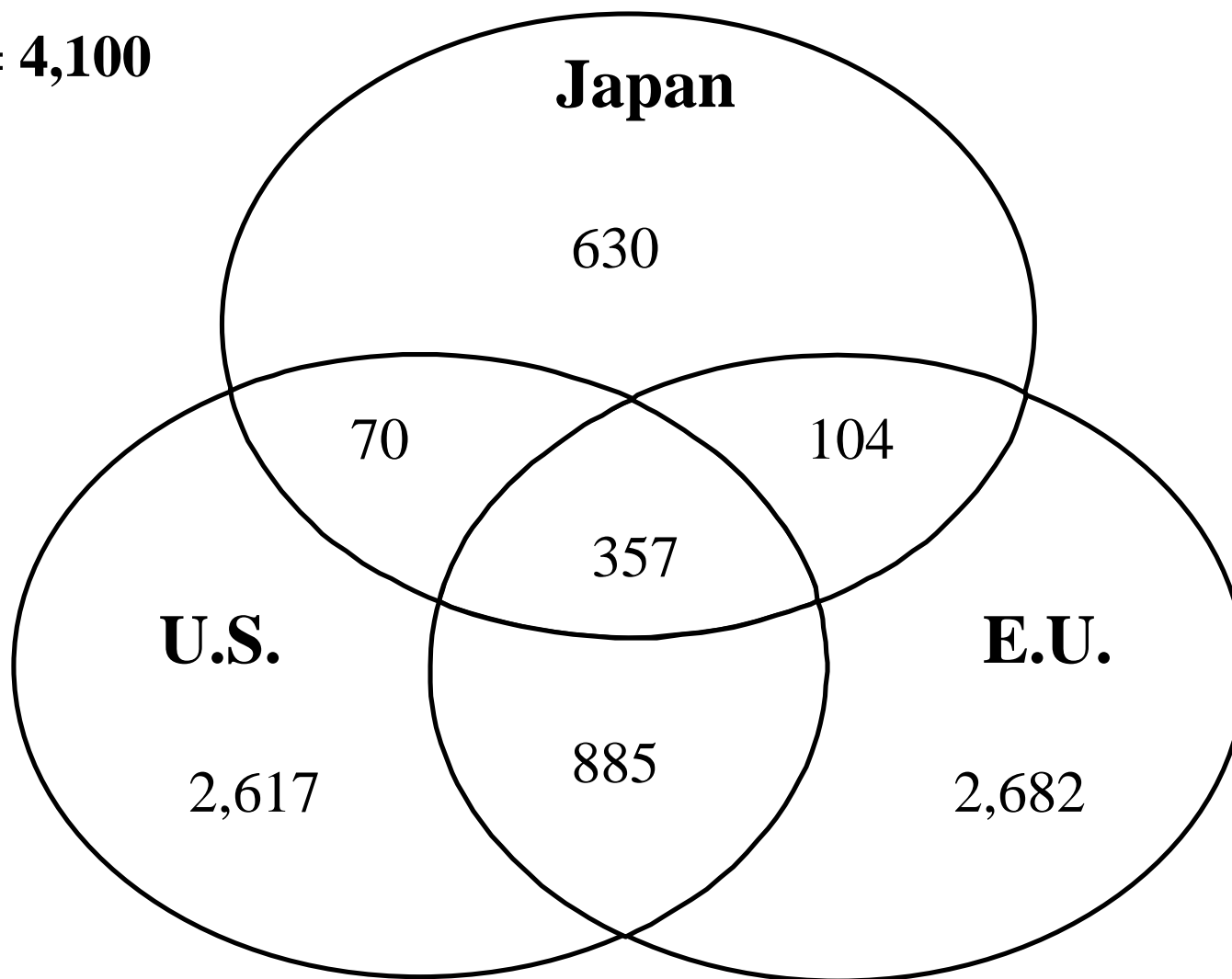
HPV Chemicals Programme

THE LIST

- ☐ Assumption that high volume chemicals may lead to high exposure
- ☐ Developed a list of HPV chemicals based on: > 1,000 tonnes in any OECD country
- ☐ Approximately 4000 chemicals on the 1997 composite OECD List
- ☐ Includes “data poor “ and “data rich” chemicals

Global Universe of HPV Chemicals

n = 4,100



HPV Chemicals Programme

Harmonized Instruments

- ☐ **SIDS**
- ☐ **Test Guidelines**
- ☐ **GLP**
- ☐ **Hazard Assessment Guidance**

HPV Chemicals Programme

Screening Information Data Set (SIDS)

- **Chemical Identity**
- **Physical Chemistry**
- **Exposure**
- **Environmental Fate and Pathways**
- **Ecotoxicity**
- **Human Toxicity**

SIDS Data Elements

① General Information

- Substance Information
- CAS Number
- Name (OECD name)
- CAS Descriptor †
- Structural Formula
- Quantity (production ranges expressed as tonnes per year)
- Use Pattern (categories and types of use)
- Sources of Exposure (exposure information)

SIDS Data Elements (cont.)

② Physical-chemical Data

- Melting Point
- Boiling Point
- Relative Density †
- Vapour Pressure
- Partition Co-efficient: n-Octanol/Water
- Water Solubility
- Dissociation Constant
- Oxidation-reduction Potential †

SIDS Data Elements (cont.)

③ Environmental Fate and Pathways

- Photodegradation (by estimation)
- Stability in Water (by estimation)
- Monitoring Data (environmental)
- Henry's Law constant (estimated)
- Transport and Distribution between Environmental Compartments including Estimated Environmental Concentrations and Distribution Pathways
- Aerobic Biodegradability

SIDS Data Elements (cont.)

④ Ecotoxicity

- Acute Toxicity to Fish
- Acute Toxicity to Daphnia (If there is concern for possible long-term effects, prolonged/chronic toxicity testing should be considered in addition to acute tests.)
- Toxicity to Algae
- If significant exposure is expected in the terrestrial environmental compartment, efforts should be made to perform appropriate terrestrial toxicity tests.

SIDS Data Elements (cont.)

⑤ Toxicological Data

- Acute Toxicity
- Repeated Dose Toxicity
- Genetic Toxicity (two end points, generally point mutation and chromosomal aberrations)
- Reproduction Toxicity (including fertility and developmental toxicity)
- Experience with Human Exposure (if available)

HPV Chemicals Programme

GUIDANCE: **INITIAL ASSESSMENT**

Environmental Effects

- ☐ **Environmental Exposure**
- ☐ **Health Effects**
- ☐ **Consumer Exposure**
- ☐ **Occupational Exposure**
- ☐ **SAR**

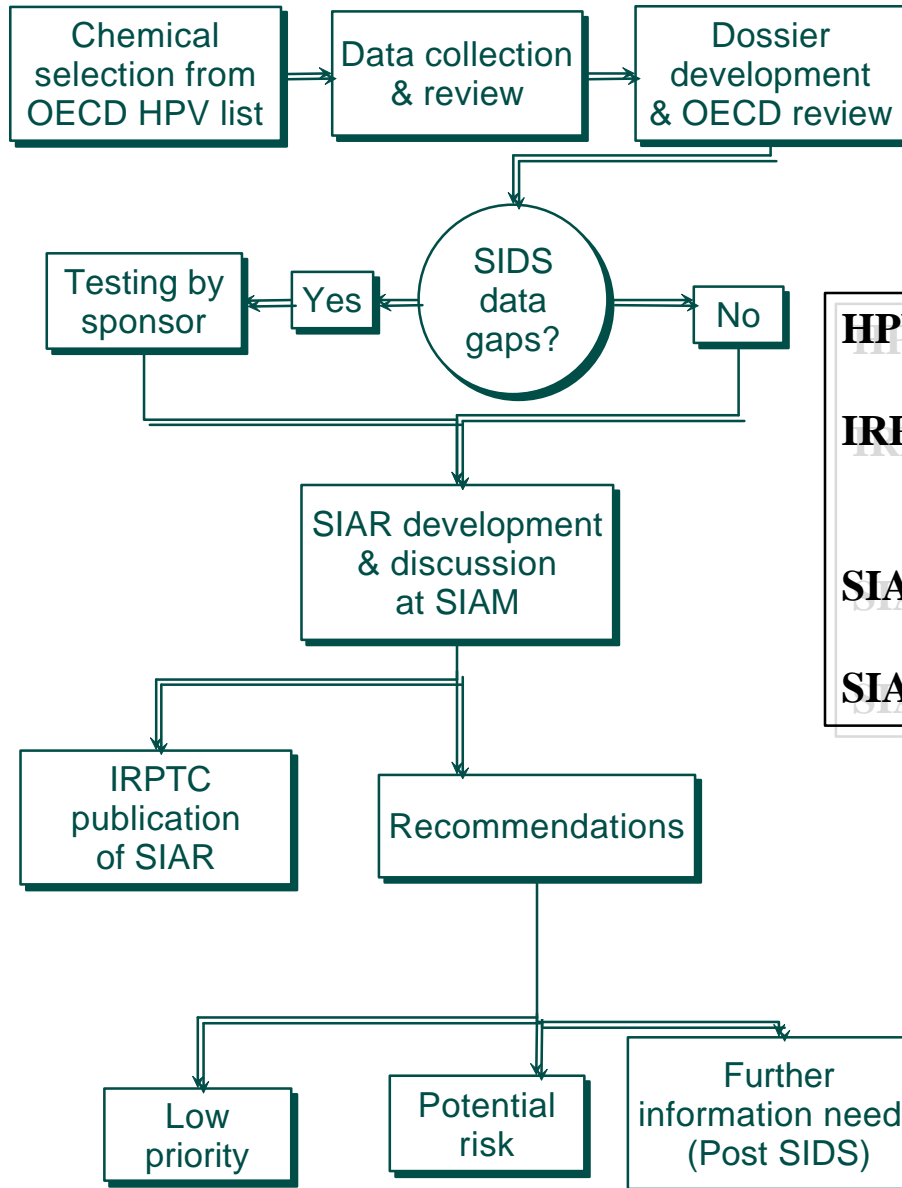
HPV Chemicals Programme

Co-operation on :

priority setting (HPV chemicals)

- ☐ **information gathering**
- ☐ **quality review**
- ☐ **SIDS testing**
- ☐ **assessment methodologies**
- ☐ **final review (assessment reports)**
- ☐ **(further testing)**
- ☐ **(risk reduction)**

SIDS Process



HPV: High Production Volume

IRPTC: International Registry of Potentially Toxic Chemicals

SIAM: SIDS Initial Assessment Meeting

SIAR: SIDS Initial Assessment Report

HPV Chemicals Programme

The Process (Sponsors)

- ❑ From the HPV List, chemicals are selected by Member countries in batches of approximately 60 for every “phase” of the programme.**
- ❑ Member countries, in consultation with their chemical industry, select chemicals for which, on a voluntary basis they will act as a Sponsor country.**
- ❑ Sponsor oversees the progress of the chemical through the process of data collection, identification of data gaps, testing and initial assessment.**

HPV Chemicals Programme

THE PROCESS (Data Collection through Initial Assessment):

- ☐ **Collection of data (readily available and unpublished) (HEDSET)**
- ☐ **Review data and prepare Screening Information Data Set (SIDS) Dossier and Testing Plan, if data are missing or inadequate**
- ☐ **Testing (if necessary)**
- ☐ **Evaluate full SIDS Dossier and prepare SIDS Initial Assessment (SIAR)**
- ☐ **SIDS Initial Assessment Meeting (SIAM)**

HPV Chemicals Programme

Conclusions and Recommendations

(examples):

- **low potential risk -> low priority for further work**
- **further information need to assess identified concerns > post-SIDS work**
- **potential risk, but adequately controlled -> low priority for further work**
- **potential risk -> priority for further action, as appropriate**

Endorsed by OECD Governments at Policy Bodies

HPV Chemicals Programme

Public Availability: all data collected or generated is made available worldwide through UNEP Chemicals (as a contribution to IOMC)

Collected data -

- in HEDSET or form
- in summaries of test reports
- in full test reports (where not claimed confidential)

Generated data -

- SIDS test reports and exposure data

Final reports -

- conclusions and recommendations (summary)
- SIAR

HPV Chemicals Programme

The Process (Sharing the Burden):

- ☐ Allocation of chemicals over countries
- ☐ Allocation within countries, over industries

SHARING THE BURDEN

THEORETICAL CONTRIBUTION TO EXISTING CHEMICALS PROGRAMME (Based on GNP)

EU	40%
USA	25%
JAPAN	24%
CANADA	3%
SWITZERLAND	2%
AUSTRALIA	2%
OTHERS	4%

SHARING THE BURDEN

REAL CONTRIBUTION TO EXISTING CHEMICALS PROGRAMME (MAY 1997)

EU	47%
USA	24%
JAPAN	22%
SWITZERLAND	3%
CANADA	3%
AUSTRALIA	1%
OTHERS	0%

STATUS OF SIDS PROGRAM

CHEMICALS

	<u>US</u>	All <u>SIDS</u>
Completed assessments:	29	166
Assessments in progress:	42	121*
Other chemicals in progress (info gathering/testing):	<u>22</u>	<u>63*</u>
Total in program as of 7/98:	93	350

(* = numbers estimated from US distribution)

HPV Chemicals Programme

SUMMARY OF TESTS CONDUCTED ON CHEMICALS FOR SIDS WORK

TESTING UNDERTAKEN

	Member countries	US	JAPAN	EU	OTHERS
Physical chemical properties	120	6.5	82	28.5	3
Environment properties	120	8.5	91	20.5	0
Ecotoxicity	163	20	98	40	5
Toxicity	234	30.5	114	73.5	16
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TOTAL	637	65.5	385	162.5	24

HPV Chemicals Programme

SUMMARY OF TESTS CONDUCTED ON CHEMICALS FOR SIDS WORK

TOXICITY TESTING UNDERTAKEN

	Member countries	US	JAPAN	EU	OTHERS
Acute	14	1	6	7	0
Repeated Dose	20	1	3	11	5
Repro/Develop screening	33	4	9	14	6
Combined test	52	8	34	10	0
1-Generation Reprotox	6	4	0	2	0
Teratogenicity	5	0	0	5	0
Genotoxicity	104	12.5	62	24.5	5
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TOTAL	234	30.5	114	73.5	16

HPV Chemicals Programme

Refocus of HPV Programme:

- 1. Define universe of chemicals**
- 2. Select chemicals (use; data availability)**
- 3. SIDS testing programme**
- 4. SIDS initial assessment programme (hazard characterisation; national exposure information)**
- 5. (Post-SIDS testing), international exposure data**
- 6. Detailed risk assessment programme (with IPCS)**

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OECD EXISTING CHEMICALS WEBSITE

[HTTP://WWW.OECD.ORG/EHS/HPV.HTM](http://www.oecd.org/ehs/hpv.htm)